

Appl. No. 09/833,328  
Amdt. dated March 15, 2005

PATENT

### REMARKS/ARGUMENTS

With entry of this amendment, claims 1-6, 8-21 and 23-31 are pending. Claims 7, 27-28 and 32-35 have been canceled, and claims 1, 9, 10, 12, 17, 18 and 30 are amended. Support for the amendments to claims 1, 17 and 30 is provided in the specification, for example, at page 9, paragraph 33. Support for the amendment to claim 9 is provided in the specification, for example, at page 8, paragraph 26. Claims 1, 10, 12, 18, and 30 are also amended to correct minor typographical errors. No new matter is added by these rejections. No amendment should be viewed as an acquiescence to any rejection.

Applicants thank Examiners Walicka and Prouty for the courtesy of telephone interview on January 6, 2005. During the interview, proposed amendments to claims 1, 9, 10, 17, 30 and 31 were discussed, based on an informal communication from Examiner Walicka. Tentative agreement was reached on the proposed amendments to the claims. Applicants also agreed to cancel the withdrawn claims.

At the conclusion of the interview, Examiner Walicka requested that Applicants submit a new paper copy of the sequence listing of December 24, 2001, to correct certain printing errors in the numbering of the nucleotides of SEQ ID NO:3. The corrected paper copy of the sequence listing was submitted in an amendment dated January 10, 2005.

Unfortunately, during the interview the undersigned was not aware a final office action had been issued. Therefore, the amendment submitted January 10, 2005, did not include the claim amendments discussed during the interview. This amendment, therefore, responds to the outstanding office action, and resubmits the sequence listing.

#### Objection to the Sequence Listing

In response to Examiner Walicka's telephonic request of January 6, 2005, Applicants submit a reformatted paper copy of the original sequence listing filed December 21, 2001. Applicants request entry of this amendment in accordance with 37 C.F.R. 1.821-1.825.

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The original paper version of the sequence listing was inadvertently printed in Times New Roman font, which improperly wrapped lines in the paper copy. The paper copy of the computer readable format (CRF) sequence listing has now been printed in Courier font to produce a paper copy of the sequence listing with proper formatting. The paper copy of the Sequence Listing is otherwise identical to the original sequence listing.

As per the PAIR report for the instant application attached herewith in Appendix B, the original CRF sequence listing was found to be technically good, and thus has not been amended.

Rejection under 35 U.S.C. Section 112, First Paragraph

Claims 1-6, 8-11, 13-21, 23-26 and 29-31 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action acknowledges that the specification describes polypeptides having a molecular weight of 180, 170, 160 and 120 kD, comprising the amino acids of SEQ ID NO:1 and having the function of cleavage of vWF. The Office Action says, however, that no description has been provided of the common functional features of all polypeptides encompassed by the claims.

Applicants respectfully disagree. Written description for a claim to a genus can be shown by "sufficient description of a representative number of species by actual reduction to practice ... or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." MPEP § 2163(II)(3)(ii).

Applicants submit the specification provides adequate written descriptive support to show Applicants were in possession of the invention recited in the pending claims. The specification describes the common structural features of four representative polypeptides, a molecular weight of between about 180 and about 120 kD as determined by SDS-PAGE under reducing conditions, and comprising SEQ ID NO:1. *See, e.g.,* Specification, pages 4-5,

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paragraphs 16-17; and Examples 1 and 4. The specification also describes the function of these polypeptides, having vWF protease activity. *See, e.g.*, Specification, page 8, paragraph 27. The specification establishes a correlation between these structural features and vWF protease activity. In particular, Example 3 shows that antibody against peptide having SEQ ID NO:1 can be used to affinity purify vWF protease from plasma. This establishes a correlation between SEQ ID NO:1 and vWF protease activity.

Further, Example 2 discloses that polypeptides comprising SEQ ID NO:1 bind to vWF. In particular, a peptide comprising SEQ ID NO:1 was used to isolate vWF from a Factor VIII/vWF complex, thus establishing a correlation between a polypeptide comprising SEQ ID NO:1 and vWF binding activity. *See, e.g.*, Specification, Example 2. Applicants therefore submit the specification discloses a description of identifying structural and functional characteristics sufficient to show Applicants were in possession of the genus of vWF protease polypeptides from plasma.

Applicants therefore respectfully request the reconsider and withdraw the rejection of claims 1-6, 8-11, 13-21, 23-26 and 29-31.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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